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16 BAXTER INTERNATIONAL INC. and
BAXTER HEALTHCARE CORPORATION

17 UNITED STATES DISTRICT COURT
18 NORTHERN DISTRICT OF CALIFORNIA
19 OAKLAND DIVISION

20 FRESenius USA, INC., a Massachusetts
21 corporation; and FRESenius MEDICAL
22 CARE HOLDINGS, INC., a New York
corporation,
23 Plaintiffs/Counter-Defendants,
v.
24 BAXTER INTERNATIONAL INC., a
Delaware corporation; and BAXTER
25 HEALTHCARE CORPORATION, a Delaware
corporation,
26 Defendants/Counter-Plaintiffs.

Case No. C-03-1431 SBA (EDL)

**FINDINGS OF FACT AND
CONCLUSIONS OF LAW
RELATING TO FRESenius'
INEQUITABLE CONDUCT
DEFENSE**

1 issued a Notice of Allowance for the claims of the '174 Application. On September 21, 1993, the
2 '174 Application issued as United States Patent No. 5,247,434. [Trial Ex. 1].

3 7. During pendency of the '174 Application, Althin filed a second application: United
4 States Patent Application No. 07/975,523 ("the '523 Application"). On May 4, 1993, the Examiner
5 rejected certain claims of the '523 Application as unpatentable over other references in combination
6 with the Lichtenstein '983 Patent. [Trial Ex. 4].

7 8. In a September 23, 1993 response, Mr. Stephens successfully distinguished the
8 Lichtenstein '983 Patent from the claims of the '523 Application. In fact, the examiner adopted Mr.
9 Stephens' reasoning as the basis for allowance. On July 9, 1994, the '523 Application issued as the
10 '476 Patent. [Trial Ex. 3].

11 9. The '434 Patent is the parent of the '476 Patent. At the time of the May 4, 1993
12 Office Action, the claims of the '174 Application were allowed, but had not issued. Thus, Fresenius
13 contends that the Lichtenstein '983 Patent was material to the co-pending '174 Application — a fact
14 allegedly brought to Mr. Stephens' attention by the May 1993 Office Action. In failing to raise the
15 Lichtenstein '983 Patent before the '434 Patent issued, Fresenius alleges that Mr. Stephens violated
16 his duty of candor to the PTO.

17 Intent to Deceive the PTO

18 10. Mr. Stephen Kunin was Fresenius' only witness on this topic. He admitted that he
19 was not offering any testimony concerning Mr. Stephens' knowledge. [June 23, 2006 Tr. 621:6-10
20 ("what was going on in Mr. Stephens' mind"); *see also* June 23, 2006 Tr. 662:24—663:16]. Further,
21 he confessed (by pre-trial deposition read to him at trial) that "***I have no evidence of intent or intent***
22 ***to deceive.***" [June 23, 2006 Tr. 659:5-6].

23 11. At best, Mr. Kunin testified simply that the May 1993 Office Action in the
24 application that led to the '476 patent was mailed to Mr. Stephens along with the Lichtenstein '983
25 patent. [June 23, 2006 Tr. 633:12-19].

26 12. That Lichtenstein was placed in the mail in May 1993, two months after the PTO
27 issued a March 1993 Notice of Allowability in the '434 application, falls far short of Fresenius'

1 burden to prove by clear and convincing evidence that Mr. Stephens believed Lichtenstein to be
 2 material to the '434 application but deliberately decided not to disclose it in an attempt to deceive
 3 the PTO.¹

4 13. Fresenius failed to offer clear and convincing evidence that Mr. Stephens knew, or
 5 should have know, Lichtenstein was applicable to the '174 Application.² Fresenius has failed to
 6 offer proof of when Mr. Stephens became aware of the Lichtenstein reference and has failed to offer
 7 any evidence that Mr. Stephens ever read the portions of the Lichtenstein that Fresenius alleges are
 8 material to the patentability of the '434 patent. In the absence of such evidence, the Court cannot
 9 find that Mr. Stephens knew of material information that was not disclosed, that he ever considered
 10 whether Lichtenstein bore on the patentability of the '434 patent (for which a Notice of Allowability
 11 had issued before Lichtenstein was cited in the '523 application), or that the reason Lichtenstein was
 12 not cited is that Mr. Stephens intended to deceive the PTO.

13 Materiality

14 14. Additionally, Fresenius has not proven Lichtenstein to be material. Mr. Kunin was
 15 qualified as an expert witness on the topic of "patent law, patent examination, policy, practice, and
 16 procedure." [June 23, 2006 Tr. 617:5-6]. He did not purport to be an expert in the relevant art who
 17 could opine whether Lichtenstein truly was material. Although Mr. Kunin attempted to identify
 18 passages in Lichtenstein supposedly inconsistent with Mr. Stephens' arguments, Mr. Kunin is not
 19 qualified to render expert testimony on what Lichtenstein actually teaches. Rather, he expressly
 20 testified that he relied upon the opinion of Mr. Causey to support his opinion concerning inequitable
 21 conduct as to the '434 patent.. [June 23, 2006 Tr. 619:25 — 620:5].

22
 23

 24 ¹ Fresenius could have called Mr. Stephens to the stand, but did not. On Thursday morning, June
 25 22, Fresenius told Baxter that it would play designated portions of Mr. Stephens' deposition.
 Then, on Thursday afternoon, Fresenius advised that it would not present Mr. Stephens'
 testimony.

26 ² At the time of the May 4, 1993 Office Action for the CIP '523 application that referenced
 27 Lichtenstein, the duty of candor and good faith owed to the PTO applied to all information
 28 "*known to that individual* to be material to patentability." See 37 U.S.C. § 1.56 (1993)
 (emphasis added).

1 16. Based on this testimony, Fresenius has not shown that Lichtenstein was not
2 cumulative of the Kerns and Rubalcaba references before the PTO. Accordingly, there was no
3 opinion of Mr. Causey for Mr. Kunin to rely upon. The Court finds that there was a failure of proof
4 on the issue of materiality. To the extent there was any substantive evidence offered on the
5 materiality of Lichtenstein, the Court finds it unpersuasive and insufficient to carry the clear-and-
6 convincing burden of proof. Accordingly, the Court cannot agree with the Advisory Jury's answer
7 to the Special Interrogatory on this element.

8
9 **II. Allegations Concerning "Extensive Innovation" Remark**

10 17. On May 29, 1998, Althin filed United States Patent Application No. 09/067922 ("the
11 '922 Application"). On June 6, 1999, the Examiner allowed Claim 36 of the '922 Application.
12 While Baxter subsequently filed Claim 36 as part of United States Patent Application No.
13 09/689503, the remaining claims of the '922 Application were abandoned. On September 4, 2001,
14 Claim 36 issued as Claim 1 of United States Patent No. 6,284,131. [Trial Ex. 7].

15 18. During prosecution of the '922 Application, Mr. Stephens made the following
16 argument:

17 Neither Lichtenstein nor Weiss provides any teaching or suggestion
18 whatsoever as to why a touch screen would be beneficial or desirable in a
19 hemodialysis machine, how a touch screen could be incorporated with a
20 hemodialysis machine, what operating parameters of the hemodialysis
21 machine could be controlled using the a touch screen, or how data
22 concerning and operating parameters of such a machine could be
23 displayed and/or changed using an touch screen. Providing a
24 hemodialysis machine with a touch screen is not the same as simply
25 adding a different style gauge to, or changing the arrangement of manual
26 controls on the front panel of the machine. Rather, providing a
27 hemodialysis machine with a touch screen requires extensive innovation in
28 hardware and software.

[Trial Ex. 13].

19. Fresenius alleges that Mr. Stephens violated his duty of candor by arguing,
"providing a hemodialysis machine with a touch screen requires extensive innovation in hardware

1 and software.” Fresenius contends that it is untrue that “extensive innovations” occurred in the
2 inventions-in-suit.

3 **Intent to Deceive the PTO**

4 20. Fresenius’ “extensive innovation” theory faces the same fatal flaws as Fresenius’
5 Lichtenstein allegations. Fresenius presented no evidence, let alone clear and convincing evidence,
6 that Mr. Stephens (1) personally believed the “extensive innovation” statement was false, or
7 (2) personally intended to deceive the PTO by making a false statement. Indeed, Mr. Kunin
8 confessed that he “do[es]n’t know” whether Mr. Stephens was speaking about the entire integration
9 of the patented hemodialysis system, as opposed to simply plugging in a touch screen. [June 23,
10 2006 Tr. 665:17-19].

11 21. In the absence of evidence that Mr. Stephens did not believe his “extensive
12 innovation” remark, Fresenius cannot prevail. Even if the “extensive innovation” statement were
13 untrue (which Fresenius has not proven), this failure of proof on the essential elements of knowledge
14 and intent dooms Fresenius’ defense.

15 **Materiality**

16 22. Once again, Fresenius also failed to prove that this kind of attorney argument to the
17 PTO was material. The Court notes that the advisory jury also reached this conclusion. Examiners
18 are “free to accept or reject” this type of attorney argument. *Life Techs. Inc. v. Clontech Labs. Inc.*,
19 224 F.3d 1320, 1326 (Fed.Cir. 2000). Furthermore, Fresenius’ assertion of untruth is integrally tied
20 to Fresenius’ repeated mischaracterization of the inventions-in-suit as involving nothing but
21 plugging a touch screen into a hemodialysis machine. That description does not accurately describe
22 the scope of the claims-in-suit, and thus the inventions. Without tackling what the inventions-in-suit
23 really are, Fresenius has not even undertaken its burden (let alone carried it) to prove that the
24 “extensive innovations” remark was a material misstatement.

CONCLUSION OF LAW

23. Under 37 C.F.R. § 1.56, “[e]ach individual associated with the filing and prosecution of a patent application owes has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability” In general, the duty of candor extends to each inventor named in the application, each attorney or agent that prepares or prosecutes the application and “every other person who is substantially involved in the preparation or prosecution of the application.”

24. Information is material when it is not cumulative to information already before the Office and either establishes a prima facie case of unpatentability or opposes an argument of patentability relied upon by the office

25. The defense of inequitable conduct arises in situations where the duty of good faith is breached by intentionally misleading the Patent Office with respect to material information. *Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1394 (Fed. Cir. 1988). Culpable acts of inequitable conduct may include a misrepresentation, a misleading statement, or an omission.

26. A holding of inequitable conduct requires a showing of two elements: (1) materiality, and (2) intent to mislead or deceive the patent examiner. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 551 (Fed.Cir.1990). Each of these elements must be shown by clear and convincing evidence. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872 (Fed.Cir. 1988); *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1344-45 (Fed.Cir. 2001).

27. If either materiality or intent is not found, then no further analysis need be performed and unenforceability must be denied. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed.Cir.1997). *See Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1261 (Fed.Cir. 2001) (failure to show either materiality or deceptive intent ends the analysis—there is no inequitable conduct).

28. If the threshold requirements of materiality and intent are established, “those fact findings are balanced to make the determination whether ‘the scales tilt to a conclusion that inequitable conduct occurred.’” *Manville*, 917 F.2d at 551 (internal citation omitted). “[T]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vica versa.” *Critikon*, 120 F.3d at 1256

29. “Materiality of an undisclosed reference does not presume an intent to deceive.” *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1442 (Fed.Cir. 1991). Nor does gross negligence alone justify an inference of intent to deceive. *Id.*; *Ajinomoto*, 228 F.3d at 1344-45; *Kingsdown*, 863 F.2d at 876; *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415 n.9 (Fed.Cir. 1987) (same); *Baxter Int’l, Inc. v. Mcgaw, Inc.*, 149 F.3d 1321, 1329 (Fed.Cir. 1998)]. Instead, “[a]n applicant’s conduct in its entirety must ‘manifest a sufficiently culpable state of mind to warrant a determination that it was inequitable.’” *Id.* at 1443 (quoting *Consol. Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804, 809 (Fed.Cir. 1990)). “In determining whether [misstatements are] intentional, ‘the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive.’”

30. After considering all of the evidence presented at trial, the Court finds that Fresenius has failed to carry its burden to prove by clear and convincing evidence that inequitable conduct occurred. *Juicy Whip Inc. v. Orange Bang Inc.*, 292 F.3d 728, 744-745 (Fed.Cir. 2002) (infringer could not prevail “because Orange Bang failed to present any evidence that the Strattons knew or considered the Bowers declaration to contain anything untrue”).

31. The ‘434 and ‘131 Patents are not unenforceable.

32. On this defense, judgment shall issue in favor of Defendants/Counterclaimants Baxter and against Plaintiffs/Counter-defendants Fresenius.

IT IS SO ORDERED:

DATED: 7/31/06


SAUNDRA BROWN ARMSTRONG
United States District Court Judge

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